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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,578

06/04/2007

Alan M. Gewirtz

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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,578	Applicant(s) GEWIRTZ, ALAN M.	
	Examiner Sean R. McGarry	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 50-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/02/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 4/07/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 50-60 and Sequences other than SEQ ID NO: 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/07/09.

It is noted that claims 10, 14, 20, 25, 31, 36, and 41 all recite "or a fragment thereof". For the purposes of applying the art below to these claims it is noted that a reasonable interpretation of this limitation leave a fragment of only one nucleotide of SE ID NO: 6. It is noted however SEQ ID NO:6 is free of the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 9, 10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al [US 6,140,125].

Taylor et al have disclosed the inhibition of Bcl-6 in cells via the administration of antisense compounds targeting bcl-6.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al [US 6,140,125] and Opalinska et al [Blood, Vol.102(11):137A-138A, 2003] in view of Tuschl et al [US2004/0259247], Noonberg et al [US 5,624,803], and Li et al [US 2002/0114784].

The invention is as set forth in the claims.

Taylor et al have taught the use of antisense compounds including ODNs for the inhibition of Bcl-6. Taylor et al teach for example:

The present invention is directed to antisense compounds, particularly oligonucleotides, which are targeted to a nucleic acid encoding bcl-6, and which modulate the expression of bcl-6. Pharmaceutical and other compositions comprising the antisense compounds of the invention are also provided. Further provided are methods of modulating the expression of bcl-6 in cells or tissues comprising contacting said cells or tissues with one or more of the antisense compounds or compositions of the invention. Further provided are methods of treating an animal, particularly a human, suspected of having or being prone to a disease or condition associated with expression of bcl-6 by administering a therapeutically or prophylactically effective amount of one or more of the antisense compounds or compositions of the invention.

Taylor et al have taught how to make antisense compounds that can be used to inhibit bcl-6 in cells and in vivo. Taylor et al have taught that the art has shown an association between bcl-6 and cancers such as lymphomas. Taylor et al do not specifically teach

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treating cancers such as lymphomas and do not teach siRNA/shRNA or vectors for the delivery of antisense or siRNA/shRNA.

Opalinska et al have taught antisense and siRNA compounds for the treatment of bcl-6 associated disease such as non-Hodgkin Lymphomas. Opalinska et al have not taught shRNAs or the use of vectors for delivery of antisense siRNA or shRNA.

Tuschl et al have taught how to make and use siRNA compounds for research and for the treatment of disease. Tuschl et al provide guidance on how one in the art can make and use siRNA to inhibit any gene with a known sequence. At paragraph [0035] it has been taught the use of vectors to express siRNA.

Li et al also teach the use of siRNA for the inhibition of a desired target gene and also teach the use of shRNA to inhibit a target gene. It is taught that siRNA and shRNA can be made to inhibit any gene with a known sequence. Li et al also teach that siRNA and shRNA can be used in the treatment of disease and that siRNA and shRNA can be expressed from vectors. Noonberg et al have taught the use of in vivo oligonucleotide generators for the expression of short RNA molecules for the treatment of disease. Noonberg et al have taught that viral vectors can be used for such vectors.

The prior art has taught that inhibition of Bcl-6 is desirable for the treatment of diseases such as lymphomas. The art has that siRNA, shRNAs and antisense molecules can be used to treat disease and furthermore the art has shown specifically the use of antisense and siRNA molecules to inhibit bcl-6. The art has taught vector delivery where one in the art would know to use a lentiviral vector to target cells such as those affected by lymphoma. The instant invention merely combines elements known in

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the prior art where there appears to be no unexpected qualities provided by the instant invention where the combining of the known elements is obvious since each element is used as taught by the prior art.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635

/Sean R McGarry/
Primary Examiner, Art Unit 1635